banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 5, 2001.

A. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303–2713:

1. First Deposit Bancshares, Inc., Douglasville, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Douglas Federal Bank, Douglasville, Georgia, upon its conversion from a federal savings bank to a chartered commercial bank.

Board of Governors of the Federal Reserve System, December 6, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00–31498 Filed 12–11–00; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0221]

Proposed Collection; Comment Request Entitled GSA Board of Contract Appeals Rules Procedure

AGENCY: GSA Board of Contract Appeals (GSBCA), GSA.

ACTION: Notice of request for public comments regarding an extension to an existing OMB Clearance (3090–0221).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Office of Acquisition Policy will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning GSA Board of Contract Appeals Rules Procedure. This information collection was published in the **Federal Register** at 65 FR 58088, on September 27, 2000 allowing for the standard 60-day public comment period. No comments were received.

DATES: Comment Due Date: January 11, 2001.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: Edward Springer, GSA Desk Officer, Room 3235, NEOB, Washington, DC 20503 and also may be submitted to: Marjorie Ashby, General Services Administration (MVP), 1800 F Street NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Margaret Pfunder, Deputy Chief Counsel, GSA Board of Contract Appeals (202) 501–0272.

SUPPLEMENTARY INFORMATION:

A. Purpose

The GSBCA requires the information collected in order to conduct proceedings in contract appeals and petitions, and cost applications. Parties include those persons or entities filing appeals, petitions, and cost applications, and government agencies.

B. Annual Reporting Burden

Respondents: 55; *annual responses:* 55; *average hours per response:* .20; *burden hours:* 6.4.

Copy of Proposal: A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 1800 F Street NW, Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: December 4, 2000.

David A. Drabkin,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 00–31515 Filed 12–11–00; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Genetic Testing

AGENCY: Office of the Secretary, DHHS.

ACTION: Request for public comment on a proposed template of genetic test information for use by health professionals.

SUMMARY: The Secretary's Advisory Committee on Genetic Testing (SACGT) was chartered to advise the Department of Health and Human Services on the medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests. SACGT recently completed its first report, Enhancing the Oversight of Genetic Tests (available at *http://www4.od.nih.gov/oba/sacgt.htm*). SACGT stated in the report's overarching principles that genetics education of health professionals and the public about the appropriate use, interpretation, and understanding of genetic test results is critical to the successful implementation of genetic testing into health care.

To inform and educate health professionals on genetic testing and their appropriate uses, SACGT is developing a template of essential information elements about genetic tests. A SACGT working group, composed of SACGT members and ad hoc experts, identified seven key data elements about a genetic test that may be valuable to health professionals considering using a genetic test for patient care. At its November 2–3, 2000 meeting, SACGT reviewed the proposed genetic test information template and recommended public comment be solicited. After consideration of public comments, SACGT's final draft of the template will be submitted to the Assistant Secretary of Health for transmittal to the Secretary of Health and Human Services.

DATES: The public is encouraged to provide written comments on the proposed genetic test information template by January 31, 2001. The following mailing address should be used: SACGT, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 103, Bethesda, Maryland, 20892. SACGT's facsimile number is 301–496–9839. Comments can also be sent via e-mail to *hagas@od.nih.gov.* All public comments received will be available for public inspection at the SACGT office between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION: Questions about this request for public comment can be directed to Dr. Susanne Haga, by e-mail (*hagas@od.nih.gov.*) or telephone (301–496–9838). The proposed template will also be posted on SACGT's website for review and comment.

SUPPLEMENTARY INFORMATION: Decades of genetics research have brought about many important medical and public health advances. The pace of discovery

in this area has enabled scientists to make rapid progress in understanding the role of genetics in many common yet complex diseases and conditions, such as heart disease, cancer, and diabetes. It also has increased knowledge that may lead to the development of new tests to identify these disease conditions in individuals, sometimes before symptoms occur. According to GeneTests, a genetic testing laboratory directory, genetic testing is clinically available for more than 400 diseases or conditions in more than 200 laboratories in the United States, and investigators are exploring the development of tests for an additional 338 diseases or conditions. However, most of the current genetic testing is for single gene disorders such as Huntington disease and cystic fibrosis.

Genetic tests can be performed for a number of purposes. Moreover, a test can be used in more than one way, such as when a test used for diagnostic purposes is also used to predict risk of disease. SACGT included the following types of testing within its definition: (1) An analysis performed on human DNA, RNA, genes, and/or chromosomes to detect heritable or acquired genotypes, mutations, phenotypes, or karyotypes that cause or are likely to cause a specific disease or condition; and (2) the analysis of human proteins and certain metabolites, which are predominantly used to detect heritable or acquired genotypes, mutations, or phenotypes. The purposes of both these types of genetic tests include directing clinical management, screening of newborns, predicting risks of disease, identifying carriers, and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations. Not included in this definition are tests that are used primarily for other purposes, but that may contribute to diagnosing a genetic disease (*e.g.,* blood smear, certain serum chemistries), and tests conducted exclusively for forensic identification purposes.

In the past, many tests were developed to detect or confirm rare genetic diseases. More recently, tests have been developed to detect mutations that may be involved in or contribute to more common, complex conditions (such as breast, ovarian, and colon cancer and cardiovascular disease), the effects of which generally do not appear until later in life. Optimally, these tests are used to predict a person's predisposition to disease where there is a family history of the disease, and, in general, such tests are not recommended for individuals without such a history. However, in the future, the use of predictive tests may expand and be offered to individuals without a family history of certain diseases and conditions, e.g., common adult-onset disorders.

Proposed Template of Genetic Test Information

Due to the wide range of genetic tests, their multiple uses and complexities, and the rapidity with which they are being developed and introduced into clinical practice, health professionals should be knowledgeable about the basic elements of a genetic test to ensure their appropriate use. A SACGT working group developed a template of seven key essential data elements about genetic tests that could serve as a framework for an informational fact sheet. This fact sheet would be analogous to reference books or fact sheets describing intended uses, risks, and benefits of drugs for health professionals. Fact sheets for genetic tests could help encourage important information exchanges between health professionals who order genetic tests and laboratorians who provide the testing services. Information that is known about a genetic test in these seven areas should be included or referenced on the fact sheet. Equally important, when data are not available for a given element, the absence of such data should be specifically noted. It will also be important for the fact sheets to be updated periodically to reflect new scientific or clinical data. If the Food and Drug Administration (FDA) or other oversight bodies become involved in the review of genetic tests prior to clinical introduction, the approved claims of the test should be stated as well.

The seven elements relate to the following areas: purpose of the test; clinical condition for which the test is performed; definition of the test; analytical validity, clinical validity, and clinical utility of the test; cost of the test and billing/reimbursement information. The seven elements are described in detail below along with the proposed sources for each element.

A. *Purpose of the Test.* SACGT proposes that the purpose of the test and the appropriate settings for offering the test should be clearly described. Examples of categories of test purposes could include predictive, carrier, prenatal, preimplantation, newborn, and diagnostic testing. Each category of test use represents a different test, even when the laboratory measurement(s) are the same. Therefore, all appropriate categories should be clearly described.

SACGT suggests that the laboratory providing the testing services should define the proper use of the test. Peer-reviewed literature as well as the laboratory's own data should be used to substantiate the appropriateness of the intended use(s) of a test. In addition, relevant clinical, professional, and health policy communities and government agencies should contribute to defining the appropriate uses of genetic tests through the development of practice standards and guidance documents.

B. *Clinical Condition for Which Test is Performed.* SACGT recommends that the clinical condition for which the test is to be performed be described. The prevalence or incidence of the disease or condition, its clinical manifestations, and prognosis to the extent known should be included in the description of the clinical condition. The testing laboratory should cite the clinical condition as part of its description of the intended use(s) of the test. Peer-reviewed literature should be referenced as appropriate. In addition, relevant clinical, professional, and health policy communities and government agencies should contribute to describing clinical manifestations, prevalence, and prognosis as appropriate.

C. *Definition of Test.* SACGT proposes that the specific laboratory measurement(s) of the test, *e.g.,* specific mutation, metabolite, enzyme activity, be described in the information template for health professionals. The description should be written in a language that would be understandable to non-laboratorians. A description of what the test measures may also assist health professionals in interpreting the results.

D. *Analytical Validity.* SACGT recommends that information regarding the analytical validity of a test be provided in the information template to health professionals. SACGT believes that a genetic test should demonstrate analytical validity before the test is used for clinical purposes. Analytical validity is defined as the ability of a test to measure or detect the analyte it is intended to measure or detect. An analyte is defined as the substance measured by a laboratory test, *e.g.,* DNA—mutation, allele, or chromosome, metabolites, or enzyme activity. Analytical validity includes analytical sensitivity (the probability that a test will detect an analyte when it is present in the sample) and analytical specificity (the probability that a test will be negative when an analyte is absent from a sample). Health professionals as well as patients should know whether a test can accurately detect the presence or absence of its intended target.

SACGT proposes that the laboratory providing the testing services supply specific information related to its assay.

As with other elements, peer-reviewed literature may be referenced to substantiate claims of test performance.

E. *Clinical Validity.* SACGT proposes that information on the clinical validity of a test be provided to health professionals. SACGT defines clinical validity as the accuracy with which a laboratory measurement predicts the presence or absence of a clinical condition. For diagnostic, prenatal, and carrier tests, accuracy could be expressed as clinical sensitivity (the probability a person with the disease, or who will get the disease, will have a positive result), clinical specificity (the probability that a test will be negative in a person who does not have or will not get the disease), positive predictive value (the probability that a person with a positive result has, or will get, the disease), and negative predictive value (the probability that a person with a negative test result does not have, or will not get, the disease). For predictive tests, SACGT proposes to define accuracy as the prediction of expressivity (the range of phenotypes associated with positive and negative test results) and age-related penetrance (likelihood of disease at a given age in test-positive individuals). In addition, health professionals should be made aware of other factors, such as environment or lifestyle, that may influence the development or prognosis of a disease or condition in an individual with a positive test result, as they may assist in their clinical management approaches.

SACGT suggests that the testing laboratory should define clinical validity as relevant to the proposed uses of the test. Peer-reviewed literature as well as the laboratory's own data should be used to substantiate the claims of clinical validity of the test. Information about the clinical validity should include, as necessary, a statement about the limitations of the available data. For example, if a test has been evaluated in only high-risk families, the absence of population-based data should be noted. More detailed consideration of clinical validity through research studies and clinical experience may contribute to the development of practice standards over time by the professional, medical, and health policy communities.

F. *Clinical Utility.* SACGT proposes that information relating to the clinical utility of a test be provided to health professionals. SACGT defines clinical utility as the contribution of the test result to improved outcome in the person tested. Clinical utility usually reflects the efficacy of clinical interventions for persons with positive test results. However, even when no interventions are available to treat or prevent the disease or condition, there may be other benefits associated with the knowledge of positive or negative test results.

If a clinical intervention is available for individuals who test positive for the disease or condition, this information should be provided to health professionals, along with the level of evidence regarding its efficacy. Other potential benefits associated with the knowledge of test results should also be described.

SACGT has not identified a specific source that would be responsible for providing information related to clinical utility. References to peer-reviewed literature or contact information for professional or patient advocacy organizations in the relevant field could be listed. Health professionals should also be active in investigating possible clinical interventions or preventive strategies. In-depth consideration of clinical utility through research studies and clinical experience will contribute to the development of practice standards and guidelines over time by professional medical and health policy communities and patient and disease advocacy organizations.

G. *Cost of Test and Billing/Reimbursement Information.* SACGT suggests that the testing laboratory provide information to health professionals on the cost of the test. At present, some genetic tests are very expensive, though, as technology advances and the use of these tests increases, it is expected that costs will decrease. If possible, the laboratory could also provide any information on billing and reimbursement policies for the test. For example, the laboratory may indicate which CPT codes should be used for billing purposes. In addition, since patients may wish to pay for the test directly due to concerns related to the confidentiality and privacy of test results, information on direct payments should be included. SACGT recognizes that laboratories may have limited information regarding reimbursement policies since these are variable and often decided over time by third-party payors. Many health insurers provide information on their reimbursement policies via their web-site or customer information services.

Questions on Which Comment Is Being Solicited

1. Do the proposed elements sufficiently address the relevant information that should be made available to health professionals about a genetic test? Are there other elements that should be added to the template? If so, please define the element and propose a specific source for the element.

2. Are the proposed sources of information appropriate for each element?

3. Who should provide information regarding the clinical utility of a genetic test?

4. Would this information template be useful to you? If so, how?

5. How would this information best be disseminated to health professionals?

6.If FDA becomes involved in the oversight of genetic tests, much of the content of the proposed fact sheets will be considered during FDA's review process. In the interim, what other review mechanisms should be considered to ensure the accuracy of the material provided in the information sheets?

Dated: December 6, 2000.

Sarah Carr,

Executive Secretary, Secretary's Advisory Committee on Genetic Testing.

[FR Doc. 00–31523 Filed 12–11–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1642]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment Registration and Listing Requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit written or electronic comments on the collection of information by February 12, 2001.

ADDRESSES: Submit electronic comments on the collection of